STATE MEDICAID DUR BOARD MEETING

THURSDAY, May 8, 2008
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:
Neal Catalano, R.Ph.
Joseph Miner, M.D.
Bradley Pace, PA-C
Colin VanOrman, M.D.
Derek Christensen, R.Ph.
Tony Dalpiaz, Pharm.D.
Dominic DeRose, R.Ph.
Mark Balk, Pharm D.

Board Members Excused:
Dan Hawley, D.D.S.
Joseph Yau, M.D.
Wilhelm Lehmann, M.D.
Bradford Hare, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:
Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Lisa Hulbert
Suzanne Allgaier, R.N.
Merelynn Berrett, R.N.
Duane Parke, R.Ph.

Other Individuals Present:
Scott Barton M.D., Molina
Steve Farmer, Amgen
Jeff Buell, J&J
Lynda Oderda, U of U
Paul Pixton, Novartis
Elaine Jensen, CMA
Craig Boody, Lilly
Kara Anderson, MHAU
Cap Ferry, LEC
Rebecca Youngblood, Student
Trish McDaid-ONeill, AstraZeneca
John Stockton, Genentech
Tony Molchan, Abbott
Barbara Boner, Novartis
Reed Murdoch, Wyeth
Alan Bailey, Pfizer

Meeting conducted by: Colin VanOrman

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1. Minutes for April 12, 2007 were reviewed. Mark Balk moved to approve the minutes. The minutes were approved with unanimous votes from Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic Derose, Joseph Miner, Bradley Pace, and Colin VanOrman.

2. Tasigna: Tim Morley addressed the Board. Tasigna is a new drug. It is for chronic myelogenous leukemia in patients intolerant or resistant to therapy that includes Gleevec. The Department is recommending a Prior Authorization based on only a diagnosis, so that it is utilized properly since it is not indicated as first-line therapy for this indication.

Paul Pixton, Medical Science Liason with Novartis addressed the Board. He has come before the Board to answer any questions. When patients start Tasigna, they would have failed at least prior therapy with Gleevec. Patients should have two things done prior to initiating therapy: they should have a CBC done at baseline and every two weeks for the first two months of therapy. They also should have baseline EKGs. After 7 days of initiating therapy, they should also have that done.

Mark Balk felt that age criteria should be included on this PA, since it is only indicated for adults. This is usually included on DUR Board PA criteria for medications that are only included for adults.

Mark Balk made a motion to accept the proposed PA criteria as amended, to include a minimum age requirement of 18 years. Tony Dalpiaz seconded the motion. The motion was approved with unanimous votes from Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic Derose, Joseph Miner, Bradley Pace, and Colin VanOrman.

3. 17-alpha Hydroxyprogesterone Caproate: Dr. Scott Barton of Molina Healthcare addressed the Board. He is a full-time practicing obstetrician. 12% of all deliveries are pre-term. A typical day in NICU for a routine premature baby is $3,000/day. This 17 hydroxyprogesterone is a method that can greatly reduce costs. There was a study done in 2003, in the New England Journal of Medicine. The principle investigator was Utah physician Dr. Michael Varner. They found that 17-p weekly reduced pre-term delivery date 33%. A study done in the Journal of Obstetrics and Gynecology in 2005 took this data and extrapolated it to national statistics. Assuming a 33% reduction of premature delivery date, that translated into 30,000 pre-term deliveries that were saved nationally that year, at an average of 31 weeks, which is 9 weeks early. Assuming a cost of $3,000 per day, $1.89 billion dollars would be the cost savings. A study on a set of twins showed no effect. There are ongoing studies for that, as well as triplets. These studies address only the direct cost of in-hospital stays for these premature babies. Other costs that weren't addressed include durable medical equipment, medical supplies, readmission, long-term cognitive physical and mental health costs, and admissions for pre-term labor for mothers that are still pregnant but are having premature labor.

Dr. Barton is part-time Medical Director for Molina Healthcare. With careful analysis, Molina took the total deliveries for 2007, and projected the savings if 17-p were implemented. Based on this data, it appears to save 155 pre-term deliveries. This does not sound like a large number, until the figures are added up. Assuming 31 weeks at delivery, $3,000 per day in the NICU per child, 17-p is a relatively cheap drug. Compounding pharmacies around the state charge anywhere between $150 to $250 per pregnancy.

There are some barriers. Pregnant patients often do not show up until it is too late. 17-p needs to be administered between 16-20 weeks gestation. There are studies suggesting that later is OK. The critical issue is not so much the timing, as the number of doses. If patients can get at least 5 doses, there seems to be an effect. Barriers to access include physician ignorance. Patients also have a habit of not showing up until the last minute for a delivery. Dr. Varner projected, using state data, around $50 million a year in cost savings. This assumes 100% identification. A significant impact can be made on the costs to the state and taxpayers.

Dr. Barton has used 17-p for about 6 months in his practice with success. This is a

medication that should make a significant impact.

Tim Morley stated that commercial preparations of this agent are not available. How long have the commercial products been unavailable? Dr. Barton did not know. He also did not know if any of the studies were published while commercial products were available.

The Board asked if other formulations of progesterone are effective for this use. Dr. Barton stated that studies have been conducted using 17-p for intramuscular and intravaginal use. However, only this particular salt has been studied for this indication.

Tim Morley mentioned that this salt does not carry an FDA approval. The Board asked if the DUR Board can even examine this without an FDA approval. Tim stated that this is why he wanted the Board to consider this agent. Also, the compounding process is fairly technical. Not every pharmacy is able to compound this. Dr. Barton said that he has identified approximately 5 pharmacies throughout the state that will prepare this.

Tim Morley asked if there are any other options available from a medication standpoint, and, if so, is it the best option? From a scientific standpoint, this is the only one proven to prevent premature delivery. The data from the studies cannot be extrapolated to other salts of progesterone.

Duane Parke asked if this agent has an NDC. The powder used to prepare the injection has an NDC, but it does not carry an FDA approval. Medicaid may consider non FDA-approved uses if it is supported in one of the approved compendia. Medicaid acknowledges that drugs are commonly used off-label, but Medicaid must be cautious in paying for this, because it is not approved for use by the federal government.

The Board asked if any other state Medicaid agencies are paying for this. Mark Balk stated that he thought North Carolina may be covering this.

Tim was only able to identify two pharmacies in the valley that compound this agent. One of the pharmacies is no longer making it. The other pharmacy was invited to address the Board, but declined.

Mark Balk asked if compounding is covered. There is a policy in place for compounded drugs. Medicaid pays one dispensing fee for each ingredient in the compound, up to 5 ingredients. Medicaid does not have a mechanism to pay a different dispensing fee for this agent. Medicaid has also been asked to reimburse several different dosage forms, but does not have recipes to indicate whether or not these dosage forms are appropriate. Dr. Barton stated that he only uses the intramuscular form, but is aware of studies supporting the use of other dosage forms.

The Board stated that Professional Compounding Centers of America (PCCA) from Dallas, TX has formulas and documentation for various dosage forms.

The Board asked Dr. Barton if he has seen adverse effects from this agent in his practice. He has not. His office uses progesterone products very commonly. Progesterone products have been used for 40 + years in Obstetrics and Gynecology.

The Board asked about their role in making a recommendation to Medicaid. First, they need

to know that the compounding pharmacies are compliant with chapter 797, that they are sterile, and inspected by the state. Medicaid agrees that this needs to be determined.

RaeDell Ashley stated that there are 3 problems that Medicaid is facing in paying for this drug. First, Medicaid needs to be satisfied that this agent is being prepared correctly. Second, the compounding pharmacies need to accept Medicaid's payment for services. Third is accepting liability in paying for this agent.

Tim Morley added that if the DUR Board had a finding that this was the direction that Medicaid should go, he would like to know what additional information would be needed by the Board to make a determination.

Mark Balk commented that from the therapeutic side of things, it is supported in the literature. ACOG supports it in a statement that came out in 2005. From a liability standpoint, Medicaid is on solid ground. The next step would be to check if the compounding is being performed appropriately. This could be incorporated into any PA requirement. The last issue is payment structure, which is not within the purview of the Board.

The Board asked if Medicaid could get a legal opinion on this. This is possible. It is also possible to incorporate sterile compounding requirements into a PA. The biggest problem will continue to be the payment structure, since it is supposed to be compounded in the pharmacy and administered in the physician's office. There have been some reports of physicians compounding this agent in their office, and Medicaid has not paid for that.

The Board asked if Medicaid is covering terbutaline for preterm labor. Medicaid does not ask why terbutaline is being used when paying a claim. Since it has a number of other indications, it is payable.

Dr. Barton stated that terbutaline is one standby treatment for preterm labor. The usual treatment is hospitalization with IV magnesium sulfate or indomethacin. There are several other medications that can be used, all of which need to be given in the hospital.

The Board clarified that there are FDA approved formulations of this progesterone salt for this indication that are not marketed. The formulation of this salt that is marketed does not carry the FDA indication.

Tim Morley stated that the Board could postpone making a decision and ask Medicaid to return with further information. One concern is identifying compounding pharmacies that can prepare this agent using appropriate sterile technique. Another concern is determining a payment mechanism for the compounding pharmacies. Dr. Barton stated that the compounding fee is only $10, and that his office could pay for that.

The Board asked to whom this drug would be administered. Dr. Barton stated that this is administered to a woman who has had previous pre-term deliveries before 37 weeks.

Tim Morley asked the Board if they are recommending a comprehensive legal opinion, decision on how to determine whether a pharmacy is using appropriate sterile technique, and a payment structure. The Board stated that this would be helpful, and asked that Medicaid return with a formal recommendation for the next meeting.

The Board asked if Jolley's compounds this agent. Dr. Barton stated that Jolley's does not.

Dr. Barton stated the commercial insurance providers send letters asking practitioners to use this agent.

4. Immunomodulators Continuation: Tim Morley addressed the Board. Last month, the Board considered Enbrel, Humira, and Orencia. The Board still needs to consider Amevive, Raptiva, Kineret, and Remicaid for review. All of these products together only represent about $1 million of usage per year. There are some slight differences between these agents. Last month, there was concern over the step therapy requirements for some of the DMARDs. The Board did make some changes when some of the other DMARDs were not appropriate for the particular disease state. Amevive is indicated for plaque psoriasis. Kineret carries requirements for rheumatoid arthritis, and has similar requirements that Enbrel and the others have. It does say in the current criteria "at least one other DMARD or second line drug". That was changed on the others last month. Raptiva is similar to Amevive, in that it is only for plaque psoriasis, but there are some differences in the criteria.

Mark Balk recommended that the Board take another look at the changes made for Enbrel during the previous month. On the Amevive and Raptiva, the FDA indications state that they are for moderate to severe plaque psoriasis, but the PA criteria state that they can be used only for severe cases. Some of the agents have the age requirement of 18 years old, some do not. The Board dropped the 10% body surface area on Enbrel last month. The Board can make these criteria sets much more consistent by basing it of the Enbrel changes. Remicaid, has multiple indications, so its criteria is more involved. Some of them also have information such as, "to be given in a clinic setting only," and goes on to talk about J-code information. Mark asked if this information is current. Tim stated that this information is current. Mark stated that "IHC" should be changed to "Select Health" to reflect the HMO's name change.

Dr. Miner pointed out that Kineret criteria require the absence of active bacterial or viral infection, malignancy, or immunosuppresive condition. It was suggested that screening for latent tuberculosis infection be included in the criteria for all of them, and that the initiation of treatment for latent TB infection be required of the patient is found to have it. All of these agents have been known to activate latent TB infections.

Tim stated that when the Board first discussed Kineret and some of the other products, requiring certain procedures as a condition of having the medication was deemed unncessary. However, if Dr. Miner feels that this is important, it can be added. Rick Sorensen stated that the concern for the PA was an appropriate diagnosis, not providing quality assurance for the provider. Dr. Miner felt that it was important, and that the requirement for absence of infection, etc. be stricken from the PA criteria, and that only a screening test for latent TB be added to all of them. Latent TB is very common, and it is not unusual for the Board to require simple tests like this as a condition of coverage. The PA nurses were instructed that this can be provided either verbally or in writing as a part of the criteria requirement.

To summarize, the TB skin test requirement should be added to the 4 agents under consideration this month, and the ones from the last month. The absence of infection will be added on all of them for the purposes of uniformity. Amevive will say "moderate to severe" and drop the body surface area requirement. The step therapy requirement on Amevive will be the same as that for Enbrel. There will also be a requirement for a

dermatology consult within 60 days, as decided last month.

With Enbrel, the Board had broken out the PA requirements by disease state. This is not the case with Remicaid. The PA nurses do find that it is helpful to have the disease states broken out. Medicaid can do this for the Remicaid.

Mark Balk moved that the changes that were discussed today and last month are prepared in draft form and brought back to the Board for final approval. Dr. Miner seconded the motion. The motion was approved with unanimous votes from Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic Derose, Joseph Miner, Bradley Pace, and Colin VanOrman.

5. Pulmonary Arterial Hypertension Drugs - Class Review: Dr. Day had written a letter to the Board expressing his concern about some of the PA criteria for this class of drugs. Dr. VanOrman stated that in looking that the criteria, he did not find the criteria very restrictive, with the exception of some of the age criteria. Tim Morley was asked to clarify Dr. Day's concerns about step therapy.

Tim Morley stated that the state website was hacked. When it was restored, an old criteria set for Ventavis was restored to the website. This resulted in a large number of phone calls to the Pharmacy Program, included one from Dr. Day. As he started to relay information, it became clear that the criteria on the website were out of date. The website is not an official state form of notification, so Medicaid looked at past official notices and corrected the information on the website to be consistent with policy. Now the class is being brought to the DUR Board for review, since these events prompted a look at the class as a whole.

Pulmonary Arterial Hypertension is a very grave condition. The medications that are used to treat are not all equivalent, do not work by the same mechanism, and do not come from the same drug class. This is one reason that the DUR Board did away with some of the step therapy requirements. Ventavis requires a single specialty nebulizer machine to administer the medication. Medicaid has adopted a Medicare payment rate for this machine, and has not met any resistance from providers. With removal of that cost barrier, it became much easier to administer the PA criteria. Aside from that, Medicaid only requires a diagnosis for the PA criteria on all of these drugs. They are very expensive medications. There is no recognizable procedure within the medical community to administer a step therapy for these drugs. Dr. Day's concern was particularly related to pediatric cases. Medicaid does not have age criteria, except on Letairis and Tracleer. Ventavis does not have a pediatric indication, but age is not required by the criteria. Tracleer and Letairis also require a classification of the disease. Should all criteria should require an age, classification, and whether or not the disease is primary or secondary?

Mark Balk suggested that the criteria include the age and the PAH criteria that the drug is indicated for, without specifying whether the PAH is primary or secondary. Cases outside of FDA approved age limits could be handled on a case-by-case basis by petition to the Board. As to the question whether or not the criteria should specify Pulmonary Arterial Hypertension or Pulmonary Hypertension as the diagnosis, the Board felt that a diagnosis of Pulmonary Hypertension was sufficient.

The Board asked if the WHO classification was necessary for inclusion in the criteria. There are different evidence-based resources with different sets of criteria. Mark Balk suggested

that the criteria include only the FDA indicated age and the diagnosis of Pulmonary Hypertension. The PA nurses state that they often have to return incomplete PA forms, because they are missing the WHO classification.

The Board asked if the substance abuse criteria for Flolan was necessary. Initially, the Board chose to require this because Flolan is given by a central line. There are other drugs that require a PA, which require IV access. Substance abuse statements are not consistently included for those PA criteria. Requiring patients with a current substance abuse issue to go to rehabilitation programs for 6 months may deny them access to necessary medication. The manufacturer has not required this as a condition of receiving the medication.

All PA requirements for PAH drugs will now require a diagnosis and age. The substance abuse statement requirement will be stricken from Flolan. Derek Christensen made this motion. Bradley Pace seconded the motion. The motion was approved with unanimous votes from Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic Derose, Joseph Miner, Bradley Pace, and Colin VanOrman.

To ensure consistency in the criteria, PA's for pulmonary antihypertensives be granted for a year, and a copy of the prescription not be required with the PA request. Derek Christensen made the motion. Mark Balk seconded the motion. The motion was approved with unanimous votes from Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic Derose, Joseph Miner, Bradley Pace, and Colin VanOrman.

Next meeting set for June 12, 2008
Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered four petitions.